4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0300]

Draft Guidance for Industry on Compliance Policy for Reporting Drug Sample Distribution Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Compliance Policy on Reporting Drug Sample Distribution Information Under the Affordable Care Act." This draft guidance is intended to provide information regarding the Agency's implementation of the drug sample transparency reporting provisions of section 6004 of the Patient Protection and Affordable Care Act. The draft guidance notifies entities covered by the reporting obligations in section 6004 that FDA does not intend to object until at least October 1, 2012, if manufacturers and authorized distributors of record (ADRs) do not submit information under those reporting provisions and that the Agency intends to provide notice before revising its exercise of discretion with respect to compliance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002 or to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Compliance Policy on Reporting Drug Sample Distribution Information." On March 23, 2010, the Affordable Care Act was signed into law. Among its many provisions, section 6004 of the Affordable Care Act amended the Social Security Act by adding section 1128H (42 U.S.C. 1320a-7i). This new section requires the submission of certain drug sample information to FDA not later than April 1 of each year, beginning April 1, 2012.

The draft guidance is intended to provide information regarding the Agency's implementation of section 6004. The draft guidance notifies entities covered by section 6004 that FDA does not intend to object until at least October 1, 2012, if manufacturers and ADRs do not submit information under section 6004 and that we intend to provide notice before revising our exercise of discretion with respect to compliance. The draft guidance also notifies covered entities that FDA plans to use its Electronic Submission Gateway (the Gateway) for submissions

under section 6004 and that revisions to allow the Gateway to receive such submissions should be complete by April 1, 2012. Should covered entities wish to make such submissions notwithstanding FDA's compliance policy, the draft guidance provides information about accessing the Gateway. The Agency expects to issue further draft guidance concerning the requirements of section 6004 later in 2012.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This draft guidance regarding Agency compliance policy refers to information collections under section 6004 that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). As noted, the Agency is also preparing a draft guidance for release later this year to provide additional information regarding submissions under section 6004. In accordance with the PRA, prior to

publication of a final guidance document, FDA intends to solicit public comment and obtain OMB approval for any new information collections under section 6004.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, or http://www.regulations.gov.

Dated: March 28, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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